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Summary of Safety and Effectiveness ImMergeTM Image Correlation System

I. Company:

Surgical Navigation Technologies

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II. Product Name: ImMerge™ Image Correlation System

III. This submission describes a software system that provides precise spatial registration of two image sets for the purpose of enhancing the imaging information presented to a physician. The resulting image sets can then be used for diagnosis and planning treatments such as image guided surgery, stereotactic radiosurgery, or radiotherapy.

IV. The ImMergeTM Image Correlation System was shown to be substantially equivalent to to other commercially available image correlation systems. Evidence of the substantial equivalence was provided.